

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-5 (Canceled)

21
 Claim 6. (Currently amended) A device for piercing the stratum corneum of a body surface to form pathways through which an agent can be introduced or withdrawn, comprising[[:]] a sheet having a least one opening therethrough and a plurality of blades extending downward therefrom, [[and]] an adhesive anchor applied to at least one surface of said sheet, wherein said adhesive anchor helps prevent [[the]] said sheet from being dislodged from [[the]] said body surface[[:]], and an agent delivery or sampling device connected to [[the]] said sheet and positioned to deliver or sample an agent through [[the]] said opening, [[the]] said agent delivery or sampling device being selected from the group consisting of an electrotransport device, a passive diffusion device, an osmotic device, and a pressure driven device[[:]], and wherein each of said plurality of blades has a substantially identical and uniform configuration.

Claim 7. (Currently Amended) The device of Claim 6, wherein [[the]] said agent comprises a polypeptide or protein.

Claims 8-29. (Canceled)

Claim 30. (Currently amended) A device for piercing the stratum corneum of a body surface to form pathways through which an agent can be introduced or withdrawn, comprising[[:]] a sheet having a least a plurality of openings therethrough, at least one of said openings having a plurality of blades located along a periphery thereof and extending downward from [[the]] said sheet, [[and]] ~~an adhesive anchor applied to at least one surface of said sheet wherein said adhesive anchor helps prevent the sheet from being dislodged from the body surface~~ anchor for anchoring said device to said body surface.[[:]] and an agent delivery or sampling device connected to [[the]] said sheet and positioned to deliver or sample [[an]] said agent through

[[the]] said opening, [[the]] said agent delivery or sampling device being selected from the group consisting of an electrotransport device, a passive diffusion device, an osmotic device, and a pressure driven device[.], and wherein each of said plurality of blades has a substantially identical and uniform configuration.

Claim 31. (Currently amended) The device of Claim 30, wherein [[the]] said agent comprises a polypeptide or protein.

Claims 53-54. (Canceled)

21
Claim 55. (Currently amended) The device of Claim 6, further comprising at least one additional anchoring means selected from the group of ~~anchoring means~~ consisting of [[: (i)] a projection extending out from [[the]] at least one blade of said plurality of blades[[;]], [[(ii)] a barb[[;]], [[(iii)] at least one opening extending through [[the]] said plurality of blades[[;]], [[(iv)] each one of the plurality of blades defines essentially a plane and wherein [[the]] said additional anchoring means ~~anchor~~ comprises a portion of [[the]] said plurality of blades being oriented at an angle of about 90° with respect to a remaining portion of [[the]] said plurality of blades[[;]], and [[(v)] wherein each one of [[the]] said plurality of blades defines essentially a plane and wherein [[the]] said additional anchoring means ~~anchor~~ comprises a portion of [[the]] said plurality of blades being oriented at an angle within a range of about 10° to about 89° with respect to a remaining portion of [[the]] said plurality of blades.

Claim 56. (Canceled).

Claim 57. (Previously presented) The device of Claim 55, wherein said projection extends out from a plane defined by at least one blade.

Claim 58. (Currently amended) ~~The device of Claim 6~~ A device for piercing the stratum corneum of a body surface to form pathways through which an agent can be introduced or withdrawn, comprising a sheet having a least one opening therethrough and a plurality of blades extending downward therefrom, an anchor for anchoring said device to said body surface and an agent

delivery or sampling device connected to said sheet and positioned to deliver or sample said agent through said opening, said agent delivery or sampling device being selected from the group consisting of an electrotransport device, a passive diffusion device, an osmotic device, and a pressure driven device, further said sheet including a prong as an additional anchor element.

Claim 59. (Currently amended) The device of Claim 6, wherein ~~[[the]]~~ said anchor is integral with an edge of ~~the at least one blade~~ said plurality of blades and in a plane defined by ~~the at least one blade~~ said plurality of blades.

31 Claim 60. (Currently amended) The device of Claim 6, wherein a portion of ~~[[the]]~~ said blades are located along a periphery of an opening through ~~[[the]]~~ said sheet.

Claim 61. (Currently amended) The device of Claim 6, wherein a portion of ~~[[the]]~~ said blades are located along peripheries of a plurality of openings through ~~[[the]]~~ said sheet.

Claim 62. (Currently amended) The device of Claim 6, further comprising a plurality of second openings through ~~[[the]]~~ said sheet ~~being spaced between the openings~~.

Claim 63. (Currently amended) The device of Claim 6, wherein ~~[[the]]~~ said device has a blade density of about 600 to about 1000 blades/cm².

Claim 64. (Currently amended) The device of Claim 6, wherein ~~[[the]]~~ said device has a blade density of at least about 800 blades/cm².

Claim 65. (Currently amended) The device of Claim 6, wherein at least a portion of ~~[[the]]~~ said blades ~~[[have]]~~ has a length sufficient to pierce the stratum corneum of ~~[[the]]~~ said body surface to a depth of at least about 25µm.

Claim 66. (Currently amended) The device of Claim 6, wherein ~~[[the]]~~ said blades are oriented approximately perpendicular to ~~[[the]]~~ said sheet.

Claim 67. (Currently amended) The device of Claim 6, wherein [[the]] said blades are oriented at an angle in [[the]] a range of about 10° to about 89° to [[the]] said sheet.

Claim 68. (Currently amended) The device of Claim 6, wherein [[the]] said blades are oriented at an angle in [[the]] a range of about 10° to about 60° to [[the]] said sheet.

Claim 69. (Currently amended) The device of Claim 6, wherein at least a portion of [[the]] said blades have a thickness in [[the]] a range of about 7 μm to about 100 μm.

Claim 70. (Currently amended) The device of Claim 6, wherein at least a portion of [[the]] said blades have a thickness in [[the]] a range of about 25 μm to about 500 μm.

Claim 71. (Currently amended) The device of Claim 6, wherein [[the]] said blades are composed of a material selected from the group consisting of metals, metal alloys, glasses, ceramics and rigid polymers.

Claim 72. (Currently amended) The device of Claim 6, wherein [[the]] said sheet and [[the]] said blades are substantially impermeable to [[the]] passage of ~~the substance~~ said agent.

Claim 73. (Currently amended) The device of Claim 6, wherein [[the]] said blades are thinner than [[the]] said sheet.

Claim 74. (Currently amended) The device of Claim 30, further comprising at least one additional anchoring means selected from the group of ~~anchoring means~~ consisting of [[(i)]] a projection extending out from ~~the at least one blade~~ at least one blade of said plurality of blades[[;]], [[(ii)]] a barb[[;]], [[(iii)]] at least one opening extending through ~~the at least one blade~~ said plurality of blades[[;]], [[(iv)]] each one of [[the]] said plurality of blades defines essentially a plane and wherein [[the]] said anchor comprises a portion of [[the]] said plurality of blades being oriented at an angle of about 90° with respect to a remaining portion of [[the]] said plurality of blades[[;]], and [[(v)]] each one of [[the]] said plurality of blades defines essentially a plane and wherein [[the]] said anchor comprises a portion of [[the]] said plurality of blades being

oriented at an angle within a range of about 10° to about 89° with respect to a remaining portion of [[the]] said plurality of blades.

Claim 75. (Canceled)

Claim 76. (Previously presented) The device of Claim 74, wherein said projection extends out from a plane defined by at least one blade.

31
Claim 77. (Currently amended) ~~The device of Claim 30~~ A device for piercing the stratum corneum of a body surface to form pathways through which an agent can be introduced or withdrawn, comprising a sheet having a least a plurality of openings therethrough, at least one of said openings having a plurality of blades located along a periphery thereof and extending downward from said sheet, an anchor for anchoring said device to said body surface, and an agent delivery or sampling device connected to said sheet and positioned to deliver or sample said agent through said opening, said agent delivery or sampling device being selected from the group consisting of an electrotransport device, a passive diffusion device, an osmotic device, and a pressure driven device, further including a prong as an additional anchor element wherein the anchor is a prong.

Claim 78. (Currently amended) The device of Claim 74, wherein ~~the anchor~~ said additional anchoring means is integral with an edge of [[the]] said at least one blade and in a plane defined by [[the]] said at least one blade.

Claim 79. (Canceled)

Claim 80. (Currently amended) The device of Claim 30, in which at least one of said plurality of openings has no blades located along [[the]] a periphery thereof wherein said openings having no blades being spaced between [[the]] a remaining plurality of said openings having blades.

Claim 81. (Currently amended) The device of Claim 30, wherein [[the]] said device has about 600 to about 1000 blades/cm².

Claim 82. (Currently amended) The device of Claim 30, wherein [[the]] said device has at least about 800 blades/cm².

Claim 83. (Currently amended) The device of Claim 30, wherein at least a portion of [[the]] said blades [[have]] has a length sufficient to pierce the stratum corneum of the body surface to a depth of at least about 25 μ m.

31
Claim 84. (Currently amended) The device of Claim 30, wherein [[the]] said blades are oriented approximately perpendicular to [[the]] said sheet.

Claim 85. (Currently amended) The device of Claim 30, wherein [[the]] said blades are oriented at an angle in [[the]] a range of about 10° to about 89° to [[the]] said sheet.

Claim 86. (Currently amended) The device of Claim 30, wherein [[the]] said blades are oriented at an angle in [[the]] a range of about 10° to about 60° to [[the]] said sheet.

Claim 87. (Currently amended) The device of Claim 30, wherein [[the]] said blades have a thickness in [[the]] a range of about 7 μ m to about 100 μ m.

Claim 88. (Currently amended) The device of Claim 30, wherein [[the]] said blades have a thickness in [[the]] a range of about 25 μ m to about 50 μ m.

Claim 89. (Currently amended) The device of Claim 30, wherein [[the]] said blades are composed of a material selected from the group consisting of metals, metal alloys, glasses, ceramics and rigid polymers.

Claim 90. (Currently amended) The device of Claim 30, wherein [[the]] said sheet and [[the]] said blades are substantially impermeable to [[the]] passage of ~~the substance~~ said agent.

Claim 91. (Currently amended) The device of Claim 30, wherein ~~[[the]]~~ said blades are thinner than ~~[[the]]~~ said sheet.

Claim 92. (Canceled)

Claim 93. (Currently amended) The device of Claim 6 wherein ~~the number~~ said sheet has openings per unit area ~~[[is]]~~ in ~~[[the]]~~ a range of at least about 10 openings/cm² to about 1000 openings/cm².

g 1
Claim 94. (Currently amended) The device of Claim 93 ~~wherein the~~ having a blade density per unit area ~~[[is]]~~ in ~~[[the]]~~ a range of about 10 blades/cm² to about 1000 blades/cm².

Claim 95. (Currently amended) The device of Claim 94 wherein ~~[[the]]~~ said blade density per unit area is in ~~[[the]]~~ a range of about 600 blades/cm² to about 1000 blades/cm².

Claim 96. (Currently amended) The device of Claim 95 wherein ~~[[the]]~~ said blade density per unit area is in ~~[[the]]~~ a range of about 800 blades/cm² to about 1000 blades/cm².

Claim 97. (Currently amended) The device of Claim 6, having a ~~in which the~~ percolation area ~~[[is]]~~ in ~~[[the]]~~ a range of about 0.005 to 0.05 cm²/cm² of body surface.

Claim 98. (Canceled)

Claim 99. (Currently amended) The device of Claim 30 wherein said sheet has ~~the number~~ openings per unit area ~~[[is]]~~ in ~~[[the]]~~ a range of at least about 10 openings/cm² to about 1000 openings/cm².

Claim 100. (Currently amended) The device of Claim 99 ~~wherein the~~ having a blade density per unit area is in ~~[[the]]~~ a range of about 10 blades/cm² to about 1000 blades/cm².

Claim 101. (Currently amended) The device of Claim 100 wherein ~~[[the]]~~ said blade density per unit area is in ~~[[the]]~~ a range of about 600 blades/cm² to about 1000 blades/cm².

Claim 102. (Currently amended) The device of Claim 101 wherein ~~[[the]]~~ said blade density per unit area is in ~~[[the]]~~ a range of about 800 blades/cm² to about 1000 blades/cm².

Claim 103. (Previously presented) The device of Claim 102 ~~in which the~~ having a percolation area is in ~~[[the]]~~ a range of about 0.005 to 0.05 cm²/cm² of body surface.

1 | Claim 104. (New) The device of Claim 30, wherein said anchor is an adhesive on a body contacting surface of said sheet, said adhesive further being on at least one surface of at least one of said plurality of blades.

Claim 105. (New) A device for piercing the stratum corneum of a body surface to form pathways through which an agent can be introduced or withdrawn, comprising a sheet having a least a plurality of openings therethrough, at least one of said openings having a plurality of blades located along a periphery thereof and extending downward from said sheet, an anchor for anchoring said device to said body surface, and an agent delivery or sampling device connected to said sheet and positioned to deliver or sample said agent through said opening, said agent delivery or sampling device being selected from the group consisting of an electrotransport device, a passive diffusion device, an osmotic device, and a pressure driven device, and wherein said anchor prevents said sheet from being dislodged from said body surface.

Claim 106. (New) A device for piercing the stratum corneum of a body surface to form pathways through which an agent can be introduced or withdrawn, comprising a sheet having a least a plurality of openings therethrough, at least one of said openings having a plurality of blades located along a periphery thereof and extending downward from said sheet, an anchor for anchoring said device to said body surface, and an agent delivery or sampling device connected to the sheet and positioned to deliver or sample said agent through said opening, said agent delivery or sampling device being selected from the group consisting of an electrotransport device, a passive diffusion device, an osmotic device, and a pressure driven device; and

yl wherein said anchor comprises a plurality of openings extending through at least one blade.
